

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

COUNCIL FOR RESPONSIBLE NUTRITION,

Plaintiff,

v.

LETITIA JAMES, in her official capacity as New  
York Attorney General,

Defendant.

No. 24-cv-1881 (ALC)

**MEMORANDUM OF LAW IN SUPPORT OF  
DEFENDANT'S MOTION TO DISMISS**

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## **PRELIMINARY STATEMENT**

In October 2023, the New York State Legislature enacted A5610, the statute at issue in this action (the “Statute”), which restricts the sale to minors of certain dietary supplements used for weight loss and muscle building. By imposing an age-based sales restriction, the Legislature reasonably sought to reduce the unsupervised use by minors of these dietary supplements given the connection of such uses to eating disorders, and to raise general public awareness about the potential dangers of these widely available—and largely unregulated—products.

Plaintiff—a trade group representing dietary supplement manufacturers and distributors—now seeks to invalidate the Statute on its face and prevent the Attorney General from enforcing it. This Court should dismiss the Amended Complaint (ECF No. 44) because Plaintiff lacks standing and because Plaintiff’s claims uniformly fail as a matter of law.

This case does not present a justiciable controversy. Plaintiff and its members have asserted only conclusory and speculative allegations of harm and have failed to meet their burden to demonstrate the concrete and imminent injuries fairly traceable to the Statute required by Article III. The Statute is a proper exercise of the State’s broad police powers to protect the public health and rationally seeks to address the growing prevalence of eating disorders by restricting the access of minors to weight loss and muscle building supplements, the use of which is associated with eating disorders and has resulted in other negative health outcomes. The Statute is not facially void for vagueness where its plain terms apply to a core of intentional conduct: the selling to minors of dietary supplements which are labeled or marketed by the manufacturer or retailer for the purpose of achieving weight loss or muscle building. The Statute’s inclusion of detailed provisions guiding courts and state officials in enforcement in determining what products may fall within the sales restriction confirms that the Statute is not impermissibly vague on its face. Manufactured questions

about how the Statute may apply in hypothetical situations at the Statute’s periphery are not properly considered in a facial challenge—the only one asserted by Plaintiff here.

Plaintiff’s First Amendment claim also fails because the Statute does not regulate commercial speech, but rather prohibits the conduct of selling dietary supplements to minors. The voluntary decisions by Plaintiff’s members to refrain from making certain claims about their dietary supplements for the purpose of evading the Statute’s restrictions do not transform the Statute into a speech regulation. Even if the Statute is assumed to regulate commercial speech, it satisfies intermediate scrutiny because the Statute’s age-based sales restriction directly and reasonably advances the State’s substantial interest in protecting public health: reducing the potential harms from the unchecked use and misuse of dietary supplements promoted for weight loss and muscle building. And the Statute is not expressly preempted by federal laws governing labeling requirements because neither federal nor state law imposes any requirements for the labeling of dietary supplements that are relevant here, and thus there can be no conflict between the two.

## **STATEMENT OF THE CASE**

### **I. STATUTORY FRAMEWORK**

Beginning in 2020, members of the Legislature sought to address the growing prevalence of the “serious public health problem” of eating disorders “affecting youth and adults of all races, ages, and genders.” Sponsor’s Mem. in Support for A10138 (2020), at 1; *accord* Sponsor’s Mem. in Support, in Bill Jacket for ch. 558 (2023), at 1-2. One chief concern for the Legislature was that an eating disorder is a mental health condition that may be identified and diagnosed based on “the presence of what clinicians call unhealthy weight control behaviors,” one of which is misusing dietary aids to try to lose weight or build muscle. *See id.* Another concern was that dietary



supplements used for weight loss or muscle building were readily available “alongside multivitamins and other supplements largely regarded as safe,” even though there had been a number of reported instances of deaths and serious harms resulting from the largely unregulated use of dietary supplements. *Id.* Modeled after longstanding age restrictions for alcohol and tobacco, which “have been demonstrated to reduce . . . consumption” of those products by adolescents, the Legislature sought to implement an age restriction for the purchase of dietary supplements used for losing weight or building muscle, to reduce the unsupervised use of these products by minors and, more broadly, to “draw attention to the life-threatening risks that come along with these widely used products.” Sponsor’s Mem. in Supp. for A10138 (2020), at 2.

Following several rounds of revisions, on October 25, 2023, the Legislature enacted A5610, the subject of this action. Ch. 558, 2023 N.Y. Laws. Consistent with the original versions of the law, the Statute provides that no person, company “or other entity shall sell or offer to sell or give away, as either a retail or wholesale promotion, . . . [a] dietary supplement for weight loss or muscle building within this state to any person under eighteen years of age.” Ch. 558, § 1, 2023 N.Y. Laws (to be codified at N.Y. Gen. Bus. Law § 391-oo(2)). As enacted, the Statute defines “dietary supplement for weight loss or muscle building” as “a class of dietary supplement as defined in section three hundred ninety-one-o of this article<sup>1</sup> that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building.” Gen. Bus. Law § 391-oo(1)(a). Exempted from the age-based sales restriction are “protein powders, protein drinks and foods marketed as containing protein unless the protein powder, protein drink or food . . . contains

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<sup>1</sup> “Dietary supplement” is defined, in relevant part, as an ingestible product that “contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid . . .” and which is labeled as a “dietary supplement” under federal law. *See* Gen. Bus. Law § 831 (renumbered from Gen. Bus. Law § 391-o).

an ingredient other than protein which would, considered alone, constitute a dietary supplement for weight loss or muscle building.” *Id.*

The Statute also contains a number of provisions clarifying its scope and guiding enforcement. In particular, the Statute states that a supplement is “labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building” where its “labeling or marketing bears statements or images that express or imply that the product will help . . . modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized” or “maintain or increase muscle or strength.” *Id.* § 391-oo(6)(b)(i)-(ii). The Statute also directs courts, in enforcement proceedings, to consider whether a dietary supplement contains certain ingredients such as a steroid, or “creatine, green tea extract, raspberry ketone, garcinia cambogia, green coffee bean extract,” or “an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building,” as the inclusion of such ingredients commonly associated with weight loss or muscle building may bring a product within the Statute’s restrictions. *Id.* § 391-oo(6)(a)(i)-(iii). Further, the Statute provides that a dietary supplement may be subject to the age-based sales restriction through the actions of the retailer by “placing signs, categorizing, or tagging the supplement with statements” suggesting that the supplement will impact weight, fat, appetite, metabolism, muscle or strength, or by “grouping the supplements with other weight loss or muscle building products in a display, advertisement, webpage, or area of the store.” *Id.* § 391-oo(6)(d)(i)-(iii).

The Statute requires brick-and-mortar retailers who directly sell covered products to the public to comply with the age-based sales restriction by requiring “proof of legal age” by means of a driver’s license or other types of identification at the point of sale. *Id.* § 391-oo(2). The Statute requires online retailers who sell covered products to use a method of mailing that requires proof

that “the person who signs to accept delivery of the shipping container” is at least eighteen years of age. *Id.* § 391-oo(4)(b).

The Statute authorizes the Attorney General, in her discretion, to enforce violations of the Statute through special proceedings in state court. Upon notice to the alleged offender, and if a court finds a violation after considering the enumerated factors set forth in the Statute, the court may issue an injunction and impose a civil penalty of no more than \$500 per violation. *Id.* § 390-oo(5). The Statute takes effect on April 22, 2024. Ch. 558, § 2, 2023 N.Y. Laws.

## II. PROCEDURAL HISTORY

On March 13, 2024, five months after the Statute was enacted, Plaintiff commenced this action, seeking a declaration that the Statute is facially invalid and an injunction barring the Attorney General from enforcing it. (ECF No. 1.) Three weeks later, on April 3, 2024, Plaintiff made an emergency motion for an order to show cause for a temporary restraining order and a preliminary injunction, seeking immediate relief ahead of the Statute’s effective date. (ECF Nos. 14-25.) On April 4, 2024, the Court denied Plaintiff’s application for a temporary restraining order and directed the Attorney General to respond to Plaintiff’s motion by April 9, 2024. (ECF No. 31.) The Court conducted a hearing on the motion on April 10, 2024, and Plaintiff thereafter amended its complaint to incorporate the additional allegations set forth in the ten declarations that were filed in support Plaintiff’s preliminary injunction motion, as directed by the Court. (ECF No. 44.)

### STANDARD OF REVIEW

Under Fed. R. Civ. P. 12(b)(1), a complaint must be dismissed for lack of subject matter jurisdiction when the “court lacks the statutory or constitutional power to adjudicate it.” *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). The party seeking to invoke the jurisdiction of the court “has the burden of proving by a preponderance of the evidence that it exists.” *Id.*

To survive a Rule 12(b)(6) motion to dismiss, the pleading must contain sufficient factual allegations which state a facially plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678- (2009). In both the Rule 12(b)(1) and (b)(6) contexts, courts must generally accept all well-pled factual allegations as true and draw all reasonable inferences in favor of the plaintiff, but may “draw on its judicial experience and common sense,” and need not credit “naked assertions” lacking in factual detail. *Id.* at 678-79.

## ARGUMENT

### I. THIS COURT LACKS JURISDICTION OVER THIS ACTION

Because federal courts are courts of limited jurisdiction, they have the “independent obligation to determine that [they have] jurisdiction before proceeding to the merits” in any case. *See In re Barclays Liquidity Cross & High Frequency Trading Litig.*, 390 F. Supp. 3d 432, 443 (S.D.N.Y. 2019). Where, as here, the plaintiff is an association, it must show that it has standing based on its own injury, or if proceeding in a representational capacity, demonstrate, among other things, that specific members have standing to sue in their own right. *See Do No Harm v. Pfizer Inc.*, 96 F.4th 106, 112-13 (2d Cir. 2024). In this case, on behalf of its members, Plaintiff asserts three types of injuries arising from the Statute: (1) threat of enforcement; (2) impairment of free speech rights; and (3) economic losses. None are sufficiently demonstrated to satisfy Article III.

First, as to threat of enforcement, Plaintiff’s members’ allegations fail to establish that they have any concrete “intention to engage in a course of conduct” prohibited by law, *Vitagliano v. County of Westchester*, 71 F.4th 130, 137-38 (2d Cir. 2023), that would subject them to a “credible threat” of enforcement, *Cayuga Nation v. Tanner*, 824 F.3d 321, 331-32 (2d Cir. 2016). The plain text of the Statute establishes that its proscriptions only apply to persons or entities who sell covered products directly to consumers, and not to the manufacturers or distributors who provide

the products to retailers or wholesalers, so long as the latter do not transact with consumers directly. *See* Gen. Bus. Law § 391-oo(2). But of the nine members of Plaintiff who provided declarations in this case, only four are from companies that directly sell products to consumers (ECF Nos. 19, 22-24)<sup>2</sup>)—the rest are from companies that merely produce or manufacture dietary supplements (ECF Nos. 16-18, 20-21). The latter companies do not face any possibility of enforcement under the Statute, and thus their imaginary fears of harm are insufficient. *See Kearns v. Cuomo*, 981 F.3d 200, 211 (2d Cir. 2020) (plaintiff lacks standing to challenge law that “does not apply to him”).

Even as to Plaintiff’s seller members, their declarations fail to demonstrate, with any level of specificity, that they have “concrete plans to perform, in the near future, the conduct that officials would consider illegal.” *See Kearns v. Cuomo*, 415 F. Supp. 3d 319, 330 (W.D.N.Y. 2019) (no standing to assert pre-enforcement challenge where plaintiff failed to provide court with “any information at all regarding his intentions”). A number of Plaintiff’s members aver that the companies purportedly must choose between “facing the risk of an enforcement action” or “overwhelmingly erring on the side of caution with respect to both the marketing and sale of dietary supplements.” *E.g.*, ECF Nos. 19 ¶ 15, 22 ¶ 18, 24 ¶ 17. But the declarations do not provide any specifics as to what the members *actually* intend to do. Nor do they identify a single product that Plaintiff’s members intend to continue selling, subject to the Statute’s age restrictions, or any product the members intend to continue selling without the restrictions that they believe may expose them to enforcement.

The absence of any factual specifics makes it impossible for the Court to determine whether the seller members’ alleged fears of enforcement are sufficiently plausible and credible, or merely

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<sup>2</sup> Because the Amended Complaint purports to incorporate the contents of the declarations (Am. Compl. ¶ 23), citations herein will be to the declarations themselves.

wholly imagined or speculative. While a plaintiff is not required to “confess that [it] will in fact violate the law,” in this case Plaintiff’s members have utterly failed to carry their burden to set forth any specific intentions of conduct from which the Court may make an objective determination on standing. *See Picard v. Magliano*, 42 F.4th 89, 98 (2d Cir. 2022).

Second, as to the First Amendment claim, since the Statute does not directly restrict or regulate speech, *see infra* at 17-20, Plaintiff and its members’ allegations that they may voluntarily alter or withhold certain of their speech concerning some dietary supplements or ingredients so as to not “trigger” the Statute’s proscriptions (ECF Doc. 15 ¶ 31), do not state a cognizable constitutional injury that is fairly traceable to the Statute. *See, e.g., Clapper v. Amnesty Int’l. USA*, 568 U.S. 398, 418 (2013); *Chrysafis v. Marks*, 573 F. Supp. 3d 831, 847 (E.D.N.Y. 2021) (“Self-inflicted injury that results from a plaintiff’s personal choices” does not confer standing). Plaintiff’s members’ conclusory claims that the Statute will “substantially chill” commercial speech, devoid of specifics as to what messages or statements are at issue, or why they would be chilled at all (*e.g.*, ECF No. 22 ¶ 18), are insufficient. It is likewise unclear from the declarations, especially the ones from the companies that describe themselves as “contract manufacturers” (*e.g.*, ECF Nos. 18 ¶ 4, 20 ¶ 4, 21 ¶ 4), that these companies engage in any labeling or marketing of dietary supplements to begin with such that they have any relevant speech that could be chilled. Nor do such manufacturers have standing to assert the speech interests of their customers. *E.g.*, ECF No. 21 ¶ 12 (alleging customers may change their labeling).

Finally, the declarations are also uniformly lacking in specific details and thus fail to demonstrate that the claims of potential economic losses—in terms of loss of customers or revenue—are actual or “sufficiently imminent” to support standing. *See Lacewell v. Office of Comptroller of Currency*, 999 F.3d 130, 146-47 (2d Cir. 2021) (allegations of anticipated loss of

future revenue speculative where plaintiff did not demonstrate loss was “inevitable” or sufficiently likely). Many of the declarants generalize “reasonably anticipat[ing] that one or more of [their] customers would reduce orders . . . or *could* exit the market,” and hypothesize about the purported harms that may occur “*if* customers of other manufacturers reduce distribution or exit the market” (e.g., ECF Nos. 18 ¶¶ 11-13, 20 ¶¶ 13-15, 15 ¶ 72 (“I believe some retailers and distributors . . . *may* decide to stop selling [affected] products”) (emphasis added), but they altogether fail to assert—even though the Statute is within days of taking effect—that any customer has actually been lost, any orders have actually been reduced, or any company has actually decided to exit the market. *See, e.g., Parker Madison Partners v. Airbnb, Inc.*, 283 F. Supp. 3d 174, 181 (S.D.N.Y. 2017) (allegation of “substantial lost business,” without specifics about “any current or potential clients that have been lost,” too conclusory to confer standing).

Because Plaintiff and its members have failed to “clearly allege facts demonstrating” that the “irreducible constitutional minimum” of standing is met here, the Court must dismiss the action for lack of subject matter jurisdiction. *See Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (internal alterations omitted).

## **II. THE STATUTE IS A PROPER EXERCISE OF THE STATE’S POLICE POWERS.**

The Legislature possesses broad police powers to enact laws aimed at protecting public health and safety, *Lyn v. Inc. Vill. of Hempstead*, 308 F. App’x 461, 464 (2d Cir. 2009) (quoting *City of Erie v. Pap’s A.M.*, 529 U.S. 277, 296 (2000)), including that of its children, *Ginsberg v. State of N.Y.*, 390 U.S. 629, 639 (1968). Such legislative actions are reviewed for reasonableness. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11, 35 (1905).

Judicial review of a state’s exercise of its police powers “is not a license for courts to judge the wisdom, fairness, or logic of legislative choices.” *Heller v. Doe*, 509 U.S. 312, 319 (1993)

(citing *FCC v. Beach Commc'ns., Inc.*, 508 U.S. 307, 313 (1993)); *Jacobson*, 197 U.S. at 30. Under the “extremely deferential” rational basis review, laws bear “a strong presumption of validity,” and those attacking the rationality of the law “must discredit any conceivable basis which could be advanced to support the challenged provision, regardless of whether that basis has a foundation in the record, or actually motivated the legislature.” *United States v. Amalfi*, 47 F.4th 114, 124-25 (2d Cir. 2022). The Legislature is not required to “actually articulate at the time the purpose or rationale supporting” its actions, or to introduce evidence to justify its policy choices. *Heller*, 509 U.S. at 320. Courts “do not demand of legislatures ‘scientifically certain criteria of legislation.’” *Ginsberg*, 390 U.S. at 642-43. Nor are legislative actions “subject to courtroom fact-finding,” and may properly “be based on rational speculation unsupported by evidence or empirical data.” *Beach Commc'ns.*, 508 U.S. at 315. In short, a statute must be upheld as long as its rationality is “at least debatable.” *Amalfi*, 47 F.4th at 125.

The Statute easily satisfies rational basis review under these settled standards. Here, one of the articulated rationales for the Statute was to address the “serious public health problem” of eating disorders, which affects “youth and adults of all races, ages, and genders.” *See* Sponsor’s Mem. in Supp., in Bill Jacket for ch. 558 (2023), at 1-2. As noted in the sponsor’s memorandum, one of the behaviors associated with eating disorders is the use of dietary supplements aimed at weight loss or muscle building, which are readily accessible to minors and generally unregulated in the marketplace. *Id.* The Statute seeks to reduce the use of such supplements by minors by “implementing an age-based restriction on sales” of these products, believing that the restrictions will also more generally “draw attention to the health risks of using these products,” which have also been shown to have been harmful to adults. *Id.*

It was plainly reasonable for the Legislature to restrict the ability of teenagers and children



to buy dietary supplements identified as promoting weight loss or muscle building as a means of protecting the public health and raising awareness of the health risks attendant to the unfettered access of these substances by a vulnerable population. *See, e.g., Graham v. Florida*, 560 U.S. 48, 68 (2010) (recognizing that minors are differently situated than adults in that minors generally have a “lack of maturity” and are “more vulnerable or susceptible to negative influences and outside pressures”); *Ginsberg*, 390 U.S. at 636 (constitutionally permissible for State to restrict sales of dangerous materials to minors that are not restricted to adults). It cannot be seriously disputed that a restriction preventing minors from directly purchasing certain dietary supplements is a rational means of reducing the unsupervised use of those products by minors—products which Plaintiff’s own members warn are “[n]ot intended for use by persons under the age of 18.”<sup>3</sup> Indeed, as the sponsor noted, laws imposing age-based restrictions on the sale of alcohol and tobacco were effective in reducing the consumption of those restricted items, *see* Sponsor’s Mem. in Support for A10138 (2020), at 2, an assertion that is well supported.<sup>4</sup>

Substantial research shows the increased prevalence of mental health conditions, including eating disorders, in recent years.<sup>5</sup> Use or overuse of “diet aids” is known to be a potential indicator of an eating disorder.<sup>6</sup> There exists ample support for the Legislature’s stated concerns about the risks to public health posed by the unchecked consumption of dietary supplements and the connection between the use (and misuse) of dietary supplements and eating disorders and other

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<sup>3</sup> *See* Nature’s Bounty, Metabolism Booster (Ingredients, Warning), *available at* <https://tinyurl.com/mav6eanb>; ECF Doc. No. 37-7 at 3 (directions for Appe-Curb warning “[n]ot for use by children”).

<sup>4</sup> *See* Defendant’s Mem. in Opp. to Pl.’s Motion for a Preliminary Injunction (ECF Doc. 36) (“Def.’s PI Opp.”) at 8 n.3.

<sup>5</sup> *See* Def.’s PI Opp. at 8 n.4.

<sup>6</sup> *See* Def.’s PI Opp. at 9 n.5.

negative public health outcomes.<sup>7</sup> Anecdotal and other research-based evidence supports the Legislature’s view that curbing the use of certain dietary supplements by minors through age-based sales restrictions will protect the public health and raise general awareness of the health risks of the use of dietary supplements.<sup>8</sup>

Plaintiff cannot undermine the reasonableness of the Legislature’s determination merely by alleging that the restricted products are “demonstrably safe,” or by proffering a study it funded and procured contending that dietary supplement use does not cause eating disorders. *See* Am. Compl. ¶¶ 180, 77 & n.13. As the Supreme Court has explained, for purposes of rational basis review, which governs here, the fact that the Legislature’s basis for action “is not universal is not controlling, for there is scarcely any belief that is accepted by everyone.” *Jacobson*, 197 U.S. at 34-35 (legislature’s determination that vaccinations protect the public health is reasonable even where plaintiff submitted offers of proof from medical professionals stating that vaccination was ineffective in preventing spread of smallpox). In this case, it is Plaintiff’s burden to conclusively refute “every conceivable basis which might support” the Statute—not the other way around. *Beach Commc’ns.*, 508 U.S. at 315. Plaintiff plainly cannot do so, and thus its *ultra vires* claim must fail.

### III. THE STATUTE IS NOT UNCONSTITUTIONALLY VAGUE ON ITS FACE<sup>9</sup>

Due process requires that laws “give the person of ordinary intelligence a reasonable opportunity to know what is prohibited” and “provide explicit standards for those who apply

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<sup>7</sup> *See* Def.’s PI Opp. at 9 n.6.

<sup>8</sup> *See* Def.’s PI Opp. at 9 n.7.

<sup>9</sup> To the extent Plaintiff is bringing its due process and First Amendment claims based on the New York Constitution (Am. Compl. ¶¶ 182, 190), they are barred by the Eleventh Amendment. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 106 (1984).

them.” *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). The void for vagueness doctrine “does not require meticulous specificity from every statute, as language is necessarily marked by a degree of imprecision.” *Thibodeau v. Portuondo*, 486 F.3d 61, 66 (2d Cir. 2007). A law is impermissibly vague not merely because it may “require[] a person to confirm his conduct to an imprecise but comprehensible normative standard, but rather in the sense that no standard of conduct is specified at all.” *Coates v. City of Cincinnati*, 402 U.S. 611, 614 (1971). To succeed on a facial challenge—the only one asserted here (Am. Compl. ¶ 1)—the plaintiff “must demonstrate that the law is impermissibly vague in all of its applications.” *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497-98 (1982). Plaintiff cannot do so because the Statute’s plain text identifies with sufficient clarity a core of conduct that is prohibited by the Statute, thereby satisfying due process as a matter of law.

Under the Statute, a dietary supplement comes within the age restriction on sales if the manufacturer’s packaging, statements, or marketing of the product identifies the supplement as aiding weight loss or muscle building by, for example, stating or suggesting that the product will “modify, maintain, or reduce body weight, fat, appetite, overall metabolism,” or will “maintain or increase muscle or strength.” Gen. Bus. Law § 391-oo(6)(b)(i)-(ii). Retailers may also bring a dietary supplement within the scope of the sales restriction, irrespective of the labeling or marketing of the product itself by the manufacturer, by grouping a dietary supplement with other weight loss or muscle building supplements through in-store displays or online categorization of the products. *Id.* § 391-oo(6)(d)(i)-(iii). The Statute also provides that dietary supplements may be subject to the sales restriction if they contain certain specifically enumerated ingredients, such as creatine or steroids, which are commonly associated with products marketed for weight loss or muscle building. *Id.* § 391-oo(6)(a)(i)-(iii). These detailed terms give businesses and individuals

clear notice of the core of the regulated conduct.

Plaintiff's own allegations confirm that the Statute sets forth comprehensible standards. Notably, the declaration from a representative of XYMOGEN, one of Plaintiff's members, demonstrates that XYMOGEN understands that the Statute's proscriptions apply to at least a subset of its products. ECF No. 23 ¶¶ 13, 17 (attesting that XYMOGEN has identified a number of "impacted products and intends to either revise product labeling and marketing to remove applicable claims and/or to age-restrict impacted products," and has "removed certain claims made in relation to six of [its] products"). And independent review of the websites associated with several of Plaintiff's members reveals a number of products that make express statements about suppressing appetite, enhancing weight loss, or boosting metabolism, or where products are grouped under the category of "weight management." *See* ECF Doc. 37-7 (screenshots of products and online sales portal). Any reasonable person would understand that these products comfortably fit within the statutory definition of a dietary supplement "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." *See* Gen. Bus. Law § 391-oo(1)(a). These clear cases, along with Plaintiff's own members' sworn statements, foreclose the claim that the Statute provides "no standard of conduct" such that it is impermissibly vague on its face. *See Vill. of Hoffman Estates*, 455 U.S. at 495 n.7.

The plain language of the Statute states that the sales restrictions apply to dietary supplements that are "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." The Supreme Court has, in considering a facial vagueness challenge to an analogous sales restriction, held that the term "marketed for use" refers to "a retailer's intentional display and marketing of merchandise," and the term's inclusion did not render the law unconstitutionally vague. *Vill. of Hoffman Estates*, 455 U.S. at 499-503 (ordinary

understanding of the term “designed and marketed for use” “requires scienter, since a retailer could scarcely ‘market’ items ‘for’ a particular use without intending that use”). Applied here, the Statute’s use of “labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building” is most naturally understood to refer to the labeling, marketing, and other representations about the product made by the manufacturer or seller. *See Orinoco Realty Co. Bandler*, 233 N.Y. 24, 30 (1922) (legislatures presumed to have knowledge of judicial interpretations of statutory terms).

There is no basis to construe the term “otherwise represented” to “cover[] a limitless world of representations, including those made by . . . unaffiliated third-parties such as social media influencers . . . in-store pharmacists, or . . . statements on the Internet,” as Plaintiff posits. *See Am. Compl.* ¶ 139. Under settled doctrines of statutory construction, courts must interpret a term in light of its surrounding text, to “avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth” to legislative acts. *Yates v. United States*, 574 U.S. 528, 543 (2015) (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)). Here, the term “represented” directly follows “labeled” and “marketed,” which, consistent with Supreme Court precedent, refer to the intentional actions by the retailer or seller of the product. *See Vill. of Hoffman Estates*, 455 U.S. at 502-03. Thus, a straightforward interpretation of “represented” likewise refers to representations made by the retailer or seller, as opposed to potential representations made by others unbeknownst to the seller subject to the sales restriction.

Even assuming there is ambiguity as to the meaning of “represented,” basic canons of statutory construction counsel in favor of construing the term to avoid constitutional problems. *See, e.g., 1256 Hertel Ave. Assocs., LLC v. Calloway*, 761 F.3d 252, 260-61 (2d Cir. 2014); *see also Kolender v. Lawson*, 461 U.S. 352, 355 (1983) (“In evaluating a facial challenge to a state

law, a federal court must, of course, consider any limiting construction that a state court or enforcement agency has proffered.”). Indeed, construing “represented” as imposing a scienter requirement on the part of the party with the potential liability undermines any claims of vagueness. *See, e.g., Vill. of Hoffman Estates*, 455 U.S. at 499 (“a scienter requirement may mitigate a law’s vagueness”); *United States v. Posters N Things Ltd.*, 969 F.2d 652, 660 (8th Cir. 1992) (statute’s “clear core of prohibited conduct” combined with scienter element “defeats a facial vagueness attack”); *United States v. Shvartsman*, No. 23-cr-307 (LJL), 2024 WL 1193703, at \*11 (S.D.N.Y. Mar. 20, 2024) (same).

That some of Plaintiff’s members purportedly cannot identify whether certain of their products will be covered by the Statute (Am. Compl. ¶¶ 172-177) likewise does not render the Statute facially unconstitutional. Such challenges are properly considered on an as-applied basis, based on the challenger’s “actual conduct and not with respect to hypothetical situations at the periphery of the statute’s scope.” *VIP of Berlin, LLC v. Town of Berlin*, 593 F.3d 179, 189 (2d Cir. 2010) (for as-applied vagueness claims, courts must focus on plaintiff’s actual conduct and not “whether a reasonable person would understand that certain hypothetical conduct or situations violate the statute”). A facial challenge is not the appropriate forum to engage in speculation about a range of hypothetical circumstances. *See Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450 (2008) (facial challenges are “disfavored” because they “often rest on speculation” and “raise the risk of premature interpretation of statutes on the basis of factually barebones records”).

Nor is the Statute facially invalid merely because the Statute directs courts to consider a non-exhaustive list of factors in determining whether a product is covered by the sales restriction, as Plaintiff claims (Am. Compl. ¶¶ 140, 146-147). *See Posters N Things Ltd.*, 969 F.2d at 655-56

(statute providing that courts should consider list of enumerated criteria “in addition to all other logically relevant factors” not void for vagueness); *Levas & Levas v. Vill. of Antioch*, 684 F.2d 446, 454 (7th Cir. 1982) (law’s use of “non-exhaustive list of factors that a court or other authority should consider” did not render it vague). And the Statute is not impermissibly vague on its face simply because it fails to define terms, since courts and regulated parties are presumed to be capable of understanding the words used in a statute by referring to their ordinary dictionary definitions. *See People v. Aleynikov*, 31 N.Y.3d 383, 397 (2018) (“When a word used in a statute is not defined in the statute, dictionary definitions serve as useful guideposts.”).

At bottom, Plaintiff’s speculative allegations about how the Statute may apply in hypothetical cases are insufficient to render the Statute facially invalid. As the Second Circuit has explained, laws “are not impermissibly vague simply because it may be too difficult to determine whether marginal cases fall within their scope.” *United States v. Sun & Sand Imports, Ltd., Inc.*, 725 F.2d 184, 187 (2d Cir. 1984). Nor can “a finding of unconstitutional vagueness . . . be based on . . . a parade of bizarre hypothetical cases: problems of that order can be resolved in challenges to the [law] as applied.” *Levas & Levas*, 684 F.2d at 451. Indeed, that judges may reasonably disagree about whether a statute applies in any given case does not render a statutory proscription unconstitutionally “shapeless” for due process purposes because “even clear rules produce close cases.” *Salman v. United States*, 580 U.S. 39, 51 (2016).

#### **IV. THE STATUTE DOES NOT VIOLATE THE FIRST AMENDMENT**

##### **A. The Statute Regulates Conduct, Not Speech.**

As set forth in its pleading, Plaintiff alleges that the Statute violates the First Amendment because it “restricts and regulates labeling, marketing and other representations concerning covered products.” Am. Compl. ¶¶ 191-192 (alleging the Statute “curtail[s]” commercial

speech).<sup>10</sup> These allegations, however, cannot be squared with the plain text of the Statute, which contains no provision regulating the content of Plaintiff’s members’ labeling or marketing of their products, or restricting Plaintiff and its members’ ability to engage in any particular speech. No provision of the Statute bans or regulates any advertising or marketing related to any products that Plaintiff’s members manufacture or sell. Instead, the Statute is directed solely towards conduct: namely, restricting the sale of certain dietary supplements to a particular class of consumers. Both before and after the Statute takes effect, Plaintiff’s members are free to label or market their products as promoting weight loss or muscle building, consistent with their business objectives to maximize sales and profit.

Regulations like the Statute which are directed at sales practices do not violate the First Amendment even if they may incidentally touch on “conduct that may have a communicative component.” *See, e.g., Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569-70 (2001) (display regulation); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 76-77 (1st Cir. 2013) (pricing discounts). A law that “neither limits what [a plaintiff] may say nor requires them to say anything . . . regulates conduct, not speech.”<sup>11</sup> *See Rumsfeld v. Forum for Academic & Inst. Rights, Inc.*, 547 U.S. 47, 60 (2006) (federal law requiring schools to allow military recruiters equal access does not regulate speech even if schools must engage in certain speech to ensure equal access); *Slattery v. Hochul*, 61 F.4th 278, 291 (2d Cir. 2023) (prohibition against

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<sup>10</sup> Plaintiff does not allege that the Statute compels any speech or imposes any other First Amendment burdens aside from these purported restrictions. *See Am. Compl.* ¶¶ 191-202.

<sup>11</sup> The First Amendment also protects against the government’s regulation of certain “expressive services,” but Plaintiff has not alleged that the sale of dietary supplements concerns anything more than commercial transactions involving “ordinary, non-expressive goods and services,” which do not implicate the First Amendment. *See 303 Creative LLC v. Elenis*, 600 U.S. 570, 599 & n.6 (2023).



personnel actions not speech regulation even if it may affect employers' ability to "advocate its views").

For example, in *Village of Hoffman Estates*, the Supreme Court held that a local ordinance prohibiting the sale of certain items "designed or marketed for use" with drugs did not infringe the First Amendment rights of the retailer, but "simply regulate[d] business behavior." 455 U.S. 489, 492-93, 495-99. Similarly, in *Lorillard Tobacco*, the Supreme Court rejected a First Amendment challenge to a state law that made it more difficult for buyers to purchase cigarettes and cigars—by prohibiting self-service displays for cigarettes and cigars and requiring buyers to have "direct contact with a sales person" and undergo the required age verification—based on the court's conclusion that the primary purpose of the law was to regulate conduct "unrelated to the communication of ideas." 533 U.S. at 569; *see also Art & Antique Dealers League of Am., Inc. v. Seggos*, 523 F. Supp. 3d 641, 646 (S.D.N.Y. 2021) (prohibition against displaying certain products is an "ordinary economic regulation of commercial activity" and imposes only "an incidental burden on speech"). Like the laws upheld in these cases, the Statute is directed to regulating conduct, and does not restrict Plaintiff's or its members' ability to communicate about their products to consumers. Plaintiff's First Amendment claim should be dismissed on this ground alone.

Although not clearly alleged, Plaintiff's theory that the Statute regulates commercial speech appears to stem from its view, and that of its members, that manufacturers and retailers may change their labeling or marketing as a means of evading the sales restrictions imposed by the Statute. *See, e.g.*, ECF No. 23 ¶ 17 (XYMOGEN representative claiming that company has decided to "remove certain claims made in relation to six of our products"); ECF No. 22 ¶ 15 (suggesting that Pharmavite may alter "both the marketing and sale of dietary supplements" in

light of the Statute). But these voluntary business decisions on the part of individual companies to alter their speech does not render the Statute itself a speech restriction. It cannot be seriously contended that the Statute sought to “deprive consumers of truthful, accurate, and FDA/FTC-regulated communications about products and ingredients that may aid them in addressing specific health concerns” (Am. Compl. ¶ 131) when the only reason manufacturers and retailers would withhold any such information would be for purposes of circumventing the Statute’s proscriptions so that they can continue selling their products to minors.

It is plain from the legislative history of the Statute that the Legislature’s focus was always on restricting the sale of certain products—dietary supplements used for weight loss or muscle building—as opposed to targeting any disfavored message. That the Statute relies on how manufacturers and retailers describe their own products, among other things, to determine which products are subject to the sales restrictions does not transform the law into a speech regulation. *See Lorillard Tobacco Co. v. Reilly*, 84 F. Supp. 2d 180, 195-96 (D. Mass. 2000) (information about the “characteristics of the commodity” offered for sale does not implicate protected speech). Because the Statute does not directly or indirectly regulate commercial speech, Plaintiff’s First Amendment claim should be dismissed, and the Court need not proceed further.

**B. Even Viewed as a Commercial Speech Regulation, the Statute Satisfies Intermediate Scrutiny.<sup>12</sup>**

Among the types of speech protected under the First Amendment, commercial speech is “more hardy, and less likely to be ‘chilled,’ *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S.

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<sup>12</sup> Plaintiff does not allege that the Statute seeks to regulate anything other than commercial speech, or that a stricter standard than intermediate scrutiny should apply. *See* Am. Compl. ¶¶ 191-201; Pl.’s Mem. in Supp. of Motion for Preliminary Injunction (ECF Doc. 25) (“Pl.’s PI Br.”) at 17-26.

469, 481 (1989), as it is “the offspring of economic self-interest,” *Central Hudson Gas & Elec. Corp. v. Public Svcs. Comm.*, 447 U.S. 557, 564 n.6 (1980). To determine whether a regulation of commercial speech is constitutionally permissible, courts must determine whether (1) the speech concerns lawful activity and is otherwise protected by the First Amendment, (2) the asserted governmental interest is substantial, (3) the regulation directly advances the asserted government interest; and (4) the regulation is no more extensive than necessary to serve that interest. *Central Hudson*, 447 U.S. at 566.

Although the Attorney General disputes that the First Amendment is implicated at all by the Statute, assuming that the Court concludes otherwise, the first prong of the *Central Hudson* test would be satisfied, and only the second, third and fourth *Central Hudson* prongs are at issue. Here, the interest underlying the Statute is the State’s stated interest in protecting the public health—more specifically, in reducing the use of dietary supplements for weight loss and muscle building by minors and promoting awareness of the potential dangers of the unregulated consumption of such dietary supplements more generally. *See* Sponsor’s Mem. in Support, at 1-2. Courts have uniformly recognized such public health interests to be substantial. *See, e.g., Lorillard Tobacco*, 533 U.S. at 569 (state has “substantial interest in preventing access to tobacco products by minors”); *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 275 (2d Cir. 2010) (state has substantial interest in protecting public health); *USA Baseball v. City of N.Y.*, 509 F. Supp. 2d 285, 303 (S.D.N.Y. 2007) (“The protection of the health and safety of high school age students is entitled to great weight”). Thus, the second prong of the *Central Hudson* analysis is met.

The last two prongs of the *Central Hudson* test seek to ensure a “fit” between the government’s stated interest and “the means chosen to accomplish those ends.” *Fox*, 492 U.S. at 480. To pass constitutional muster, the “fit” needs not be “perfect,” but merely “reasonable,” and

does not need to be “the single best disposition” or “the least restrictive means.” *Id.*

There can be no dispute here that the public health problems sought to be addressed by the Statute—the prevalence of eating disorders, and the health harms from the unregulated use of dietary supplements used for weight loss and muscle building—are real. Nor has Plaintiff alleged to the contrary. *See* Am. Compl. ¶¶ 102-106 (merely alleging studies that show “low” rates of use of dietary supplements by adolescents); Pl.’s PI Br. at 21 (acknowledging eating disorders are “unquestionably a real harm”). In any event, the legislative record and widespread reports confirm the existence of these threats to the public health. *See supra* at 11-12 & nn. 5-8. The State’s “accumulated, commonsense judgment” about the existence of these harms is entitled to deference. *See Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 509 (1981).

The third *Central Hudson* prong is satisfied because the Statute directly and materially advances the State’s interests in addressing these harms. There is ample evidence in the legislative record and the public health discourse that the use of dietary supplements for weight loss and muscle building is a behavior that is associated with eating disorders. *See supra* at 11-12 & nn. 6-8. And empirical evidence has demonstrated that imposing age-based restrictions on products is effective in meaningfully reducing the access to those restricted products by minors. *See supra* at 11 n.4; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (suggesting that purchasing restrictions are likely to be a more direct means of achieving the state’s goal of reducing alcohol consumption than banning certain types of price advertising).

Plaintiff’s allegations that the scientific studies connecting dietary supplement use to eating disorders are purportedly “flawed” (Am. Compl. ¶ 133) are insufficient to invalidate the Statute. Even if such allegations are true, as the Supreme Court has recognized, state laws may satisfy intermediate scrutiny by reliance on “studies and anecdotes . . . or even . . . based solely on history,

consensus, and ‘simple common sense.’” *Lorillard Tobacco*, 533 U.S. at 555 (quoting *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995)). The Statute easily passes constitutional muster on these bases, as there exists ample scientific and anecdotal evidence supporting a connection between the sales restriction imposed by the Statute and the public health interests it seeks to advance. *See supra* at 11-12.

Nor are Plaintiff’s criticisms of the Statute’s restrictions as overinclusive and underinclusive enough to establish that the Statute fails to satisfy the “reasonable fit” test. *See* Am. Compl. ¶¶ 197-198. That the Statute is not the perfect means of achieving the State’s interests does not render the Legislature’s chosen means constitutionally infirm. *See, e.g., Vugo, Inc. v. City of N.Y.*, 931 F.3d 42, 52-53, 58 (2d Cir. 2019) (city’s in-ride advertising ban for taxis materially advances the city’s interest in reducing passenger annoyance despite exceptions). Where, as here, the challenged law is a logical and effective means of addressing a valid and substantial government interest, it does not fail the “fit” prong of the *Central Hudson* test merely because the Statute does not solve the entirety of the perceived problem. “The government is not required to ‘make progress on every front before it can make progress on any front.’” *Vugo*, 931 F.3d at 54.

Finally, the Statute satisfies the fourth *Central Hudson* requirement: the Statute does not “burden substantially more speech than is necessary” in advancing the State’s interests in protecting the public health and addressing the prevalence of eating disorders. *See Vugo*, 931 F.3d at 58. As explained *supra*, the Statute does not restrict marketing or labeling related to weight loss or muscle building, or mandate any disclosures, and thus it does not directly burden or impact speech at all. It was plainly not the intent of the Legislature that Plaintiff’s members will refrain from certain marketing or labeling practices to evade the Statute’s sales restrictions. *Central Hudson* “does not require that there be no conceivable alternative to the government’s approach,

or that the government’s regulation be the least restrictive means of advancing its asserted interests.” *Vugo*, 931 F.3d at 58 (quoting *Fox*, 492 U.S. at 478).

Here, the Legislature made the reasonable decision to address the public health concerns it perceived by imposing an age-based restriction on the sale of certain dietary supplements, based on its belief that the restriction would reduce the use of such supplements by minors and generally raise public awareness about the safety concerns surrounding the dietary supplement market. *Central Hudson*’s reasonable fit test is not a means for courts to “second-guess” the measured policy judgments of the Legislature; rather, the State should be “afforded considerable leeway in determining the appropriate means to further a legitimate government interest.” *See Vugo*, 931 F.3d at 58. Plaintiff’s First Amendment claim should accordingly be dismissed.

## **V. THE STATUTE IS NOT PREEMPTED BY FEDERAL LAW**

The sole source of Plaintiff’s preemption claim (Am. Compl. ¶ 216) is 21 U.S.C. § 343-1(a), which expressly preempts any state “requirement respecting any claim [about nutritional levels and health benefits] . . . made in the label or labeling of food that is not identical to the requirement of [21 U.S.C.] § 343(r).” 21 U.S.C. § 343-1(a). Section 343(r), in turn, governs voluntary claims about health-related benefits that dietary supplement manufacturers are permitted to make about their products. *Id.* § 343(r)(1)(B) (claims describing “the relationship of any nutrient . . . to a disease or health-related condition”), (r)(6) (providing that dietary supplement labels *may* make certain claims about the health-related benefits provided manufacturer has “substantiation that such statement is truthful and not misleading,” among other things).

The plain text of the federal statutes relied on by Plaintiff forecloses Plaintiff’s express preemption claim. Neither federal nor state law imposes any “requirement” as to what health-related statements Plaintiff’s members must make on their labeling. *See* 21 U.S.C. § 343-1(a).

Indeed, the Statute in no way prohibits or otherwise restricts the ability of Plaintiff or its members to make any statements concerning the purported health-related benefits of a dietary supplement that they are permitted to make under federal law. There is thus simply no basis for express preemption. *See N.Y. State Rest. Ass’n v. N.Y. City Bd. of Health*, 556 F.3d 114, 123-31 (2d Cir. 2009) (ordinance requiring restaurants to disclose calorie counts not preempted by federal law governing nutritional content labeling); *Grocery Mfrs. Ass’n v. Sorell*, 102 F. Supp. 3d 583, 612-15 (D. Vt. 2015) (state law that did not require changes to existing labeling required by federal law not preempted).

There is likewise no basis for conflict preemption. Here, it is not “physically impossible” to comply with the age-based sales restrictions imposed by the Statute and the standards governing the voluntary health-related claims set forth in federal law. *See, e.g., Mutual Pharms. Co. v. Bartlett*, 570 U.S. 472, 503 (2013). Nor do the Statute’s restrictions on sales of certain dietary supplements pose “an obstacle to the accomplishment and execution of the full purposes and objectives of” federal law, *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), which merely permits certain voluntary health-related claims and sets the standards for such claims if they are made. 21 U.S.C. § 343(r)(6).

### CONCLUSION

The Court should dismiss the Amended Complaint in its entirety with prejudice.

Dated: New York, New York  
April 12, 2024

Respectfully submitted,

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